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TRANSMITTAL		Application Number 10/.724,397; Confirmation 8		7; Confirmation 8892	
TRANSMITTAL FORM		Filing Date		12/1/2003	
		First Named Inventor		Goldenberg	
		Art Unit		1618	
(to be used for all correspondence after	initial filing)	Examiner Name		Jagadishw	ar Samala
Total Number of Pages in This Submiss		Attorney Docket N	umber	330687	
ENCLOSURES (check all that apply)					
Fee Transmittal Form	☐ Drawing(s			After Allo	owance Communication to TC
Fee Attached		-related Papers			Communication to Board
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket	t No.: 77957-330687		
In re Applica	ation of:) Examiner:	Jagadishwar Samala
Gold	enberg) Art Unit:	1618
Serial No.:	10/724,397) Confirmation No.:	8892
Filed:	12/1/2003)	
For:	Alpha or Beta Emitters Attached to Fragments in Radioimmunotherapy)	

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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97(B)(3) AND 1.98

Dear Sir:

The Examiner is requested to consider the references noted on the enclosed Form PTO/SB/08a-b during examination of the above-identified patent application. These references are submitted for the Examiner's consideration and are submitted pursuant to the duty of disclosure under 37 C.F.R. § 1.56. In submitting these references, no representation is made or implied that the references are or are not material to the examination of the application. The Examiner is encouraged to make his or her own determination of materiality. In accordance with 37 C.F.R. § 1.98(a)(2)(i), copies of the U.S. references are not provided herewith.

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Atty. Docket No.: 77957-330687 Serial No.:

10/724,397

Date: October 5, 2006

Respectfully submitted, FAEGRE & BENSON LLP

Richard A. Nakashima Registration No. 42,023 Attorney for Applicant

CUSTOMER NO. 35657 FAEGRE & BENSON LLP Tel: (303) 447-7728

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Complete if Known					
Application Number	10/724,397; Confirmation 8892				
Filing Date	12/1/2003				
First Named Inventor	Goldenberg				
Art Unit	1616				
Examiner Name	Jagadishwar Samala				
Attorney Docket Number	330687				

	U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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	1	WO 96/29087	9/26/1996	Behr		
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Substitute for form 1449B/PTO Complete if Known 10/724,397; Confirmation 8892 Application Number INFORMATION DISCLOSURE Filing Date 12/1/2003 STATEMENT BY APPLICANT First Named Inventor Goldenberg Art Unit 1616 (Use as many sheets as necessary) Examiner Name Jagadishwar Samala Sheet Attorney Docket Number 330687

		NON PATENT LITERATURE DOCUMENTS	γ
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	3	CASEY, J. L., et al., "Clearance of yttrium-90-labelled anti-tumour antibodies with antibodies raised against the 12N4 DOTA macrocycle" British Journal of Cancer (1998) 78(10), 1307-1312 XP-000986994	
	4	ROWLINSON-BUSZA, Gail, et al., "90Y-Labeled Antibody Uptake by Human Tumor Xenografts and The Effect of Systemic Administration of EDTA" Int. J. Radiation Oncology Biol. Phys., Vol. 28, No. 5, pp. 1257-1265, 1994	
	5	DENARDO, Sally J., et al., "Yttrium-90/Indium-111-DOTA-Peptide-Chimeric L6: Pharmacokinetics, Dosimetry and Initial Results in Patients with Incurable Breast Cancer" Anticancer Research 17: 1735-1744 (1997)	
	6	ADAMS, G. P., et al., "Delivery of the a-Emitting Radioisotope Bismuth-213 to Sold tumors via Single-Chain Fv and Diabody Molecules" Nuclear Medicine & Biology, Vol. 27, pp. 339-346, 2000	
	7	BEHR, THOMAS M., et al., "High-Linear Energy Transfer (LET) a versus Low-LET B Emitters in Radioimmunotherapy of Solid Tumors: Therapeutic Efficacy and Dose-limiting Toxicity of 213Bi-versus 90Y-labeled CO17-1A Fab' Fragments in a Human Colonic Cancer Model" Cancer Research 59, 2635-2643, June 1, 1999	
	8	GOVINDAN, SERENGULAM V., et al., "90 Yttrium-Labeled Complementarity-Determining-Region-Grafted Monoclonal Antibodies for Radioimmunotherapy: Radiolabeling and Animal Biodistribution Studies" Bioconjugate Chem. 1998, 9, 773-782	
	9	WONG, JEFFREY Y. C., et al., "A Phase I Radioimmunotherapy Trial Evaluating 90 Yttrium-labeled Anti- Carcinoembryonic antigen (CEA) Chimeric T84.66 in Patients with Metastatic CEA-producing Malignancies" Clinical Cancer Research, Vol. 6, 3855-3863, October 2000	
	10	DAVIS, ILA A. et al., "Radioimmunotherapy Using Vascular Targeted 213Bi: The Role of Tumor Necrosis Factor a in the Development of Pulmonary Fibrosis" Clinical Cancer Research 3160s Vol. 5, 3160s-3164s, October 1999 (Suppl.)	,
	11	WATANABE, NAOYUKI, et al., "CaNa2 EDTA for Improvement of Radioimmunodetection and Radioimmunotherapy with 111In and 90Y-DTPA-Anti-CEA MAbs in Nude Mice Bearing Human Colorectal Cancer" The Journal of Nuclear Medicine, Vol. 41, No. 2, February 2000, pgs 338-344	
	12	JONES, SHAUN B. et al. "Evaluation of Dithiol Chelating Agents as Potential Adjuvants for Anti-IL-2 Receptor Lead or Bismuth Alpha Radioimmunotherapy" Nuclear Medicine & Biology, Vol. 23, pp. 105-113, 1996	
	13	GOODWIN, D. A., et al., "Monoclonal antibody hapten radiopharmaceutical delivery" Nuclear Medicine Communications 7, 569-580 (1986)	

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Substitute for form 1449B/PTO Complete if Known Application Number 10/724,397; Confirmation 8892 INFORMATION DISCLOSURE Filing Date 12/1/2003 STATEMENT BY APPLICANT First Named Inventor Goldenberg Art Unit 1616 (Use as many sheets as necessary) Examiner Name Jagadishwar Samala

Sheet

	,	NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	14	JUWEID, MALIK E., et al., "Phase I/II Trial of 131I-MN-14 F(ab)2 Anti-Carcinoembryonic Antigen Monoclonal Antibody in the Treatment of Patents with Metastatic Medullary Thyroid Carcinoma" Cancer April 15, 1999, Vol. 85, No. 8, pg. 1828-1842	
	15	KARACAY, et al., "Development of a StreptavidinAnti-Carcinoembryonic Antigen Antibody, Radiolabeled Biotin Pretargeting Method for Radioimmunotherapy of Colorectal Cancer. Reagent Development" Bioconjugate Chem. 1997, 8, 585-594	
	16	BEHR, THOMAS M., et al., "Phase I/II Clinical Radioimmunotherapy with an Iodine-131-Labeled Anti- Carcinoembryonic antigen Murine Monoclonal Antibody IgG" The Journal of Nuclear Medicine, Vol. 38, No. 6, June 1997, pgs. 858-870	
	17	ULLEN, ANDERS, et al. "Use of Anticytokeratin Monoclonal Anti-Idiotypic Antibodies to Improve Tumor: Nontumor Ratio in Experimental Radioimmunolocalization" Cancer Research (Suppl.) 55, 5868s-5873s, December 1, 1995	
	18	ONG, GAIK LIN, et al. "The fate of antibodies and their radiolabels bound to tumor cells in vitro: the effect of cross-linking at the cell surface and of anti-idiotype antibodies" Cancer Immunol Immunotherapy (1994) 39: 325-331	
	19	SHARKEY, ROBERT M., et al., "Clinical Evaluation of Tumor Targeting with a High-Affinity, Anticarcinoembryonic-Antigen-Specific, Murine Monoclonal Antibody, MN-14" Cancer March 15, 1993, Vol. 71, No. 6 pgs. 2082-2846	
	20	PIMM, M. V., et al. "Influence of syngeneic monoclonal anti-idiotypic antibodies to murine Monoclonal antibodies against turnour-associated antigens on the biodistribution of their target antibodies and their fragments" J Cancer Res Clinical Oncology (1993) 119:408-414 pgs 408-414	
	21	SCHIELE, J., et al., "The effect of unlabelled monoclonal antibody (mAb) on the biodistribution of 131I-anti- idiotype mAb in murine B cell lymphoma" Radiotherapy and Oncology, 24 (1992) 169-176 pgs. 169-176	
	22	SHARKEY, ROBERT M., et al., "Enhanced Clearance of Radiolabeled Murine Monoclonal Antibody by a Syngeneic Anti-Idiotype Antibody in Tumor-Bearing Nude Mice" Int. J. Çancer 51, 266-273 (1992)	
	23	GOLDENBERG, DAVID M., et al., "Targeting, Dosimetry, and Radioimmunotherapy of B-Cell Lymphomas with lodine-131-Labeled LL2 Monoclonal Antibody" Journal of Clinical Oncology, Vol. 9, No. 4 (April 1991), pp. 548-564	
•	24	STEWART, J. SIMON W., et al., "Clearance of 131I-labeled Murine Monoclonal Antibody from Patients' Blood by Intravenous Human Anti-Murine Immunoglobulin Antibody" Cancer Research 50, 563-567, February 1, 1990	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	12/1/2003	
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(Use as many sheets as necessary)			necessary)	Examiner Name	Jagadishwar Samala	
Sheet	4	of	4	Attorney Docket Number	330687	

NON PATENT LITERATURE DOCUMENTS							
Examiner Initials *	Cite No.1						
	25	BLUMENTHAL, RASALYN D. et al., "Reduction by Anti-Antibody Administration of the Radiotxicity Associated with 1311-Labeled Antibody to Carcinoembryonic Antigen in Cancer Radioimmunotherapy" Journal of the National Cancer Institute Vol. 81, No. 3, February 1, 1989					
	26	PIMM, M. V., et al., "The Influence of Syngeneic Anti-Idiotypic Antibody on the Biodistribution of an anti-tumour monoclonal Antibody in Balb/c Mice" Int. J. Cancer: 43, 147-151 (1989)					
	27	SHARKEY, ROBERT M., et al., "Factors Influencing Anti-Antibody Enhancement of Tumor Targeting with Antibodies in Hamsters with Human Colonic Tumor Xenografts" Cancer Research 48, 2005-2009, April 15, 1988					
	28	GOLDENBERG, DAVID M., et al., "Anti-Antibody Enhancement of Iodine-131 Anti-CEA Radioimmunodetection in Experimental and Clinical Studies" The Journal of Nuclear Medicine, Volume 28, Number 10, October 1987, pp 1604-1610					
	29	SHARKEY, Robert M., et al. "Clinical Evaluation of Tumor Targeting with a High-Affinity, Anticarcinoembryonic- Antigen-Specific, Murine Monoclonal Antibody, MN-14" Cancer March 15, 1993, Volmue 71, No. 6, pp 2082-2096					
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